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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,458	08/11/2000	Yumi Matsuzaki	195675US0	8810

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EXAMINER

GUZO, DAVID

ART UNIT PAPER NUMBER

1636

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/636,458

Applicant(s)

MATSUZAKI ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9,10,12-16,18,20 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9,10,12,13,18,20 and 29 is/are rejected.
- 7) ☒ Claim(s) 14-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/11/00 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **Detailed Action**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/14/04 has been entered.

The substitute Specification filed 5/14/04 is accepted and has been entered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-10, 12-13, 18, 20 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:4 and a plasmid comprising SEQ ID NO:4 and a method of isolating a plasmid comprising SEQ ID NO:4, does not reasonably provide enablement for nucleic acids and plasmids comprising sequences at least 90% or at least 99% homologous to SEQ ID NO:4 or a method for isolating a plasmid comprising a sequence encoding a polypeptide having Rep activity and is at least 90% homologous to SEQ ID NO:4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants claim an isolated polynucleotide or plasmid comprising a gene encoding a Rep protein, said Rep protein comprising an amino acid sequence that is at least 90% or at least 99% homologous to the amino acid sequence of SEQ ID NO:4 and a method of isolating said plasmid. Applicants provide no disclosure of the functional motifs essential for activity of Rep proteins, regions of Rep proteins essential for activity, etc. Applicants provide a method for identifying whether a given polypeptide has Rep activity. This enablement rejection is based upon applicants' not teaching the skilled artisan how to make the claimed polynucleotides, only how to identify the claimed polynucleotides.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based upon a single factor, but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

Unpredictability of the art. The art with regard to making polynucleotides homologous to SEQ ID NO:4 at the recited levels and having Rep activity must be considered unpredictable given that applicants have not identified the essential structural motifs necessary for Rep activity. Essentially, the skilled artisan would need

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to practice trial and error experimentation in the process of randomly altering the sequence of SEQ ID NO:4 in order to try to produce a molecule with Rep activity. Given the size of the molecule involved (almost 500 amino acids) and given that changes in one or a few amino acids can have profound influences in protein activity (for example, Broun et al., Science, 1998, Vol. 282, pp. 1315-1317 recites that as little as four amino acid substitutions can convert an oleate 12-desaturase to a hydroxylase), it must be considered unpredictable as to whether any particular molecule at least 90% or 91% or 92% etc. would possess Rep protein activity.

State of the art. The state of the art with regard to proteins with Rep activity is poorly developed. No art exists regarding functional motifs of Rep proteins, isolation of Rep proteins from coryneform bacteria, etc.

Number of working examples. Applicants present four examples of Rep proteins from the species *C. thermoaminogenes*.

Scope of the claims. The claims are broad and read on millions of different nucleic acid molecules encoding the recited Rep proteins.

Amount of guidance provided. Applicants provide no guidance on the nature of Rep proteins other than the four disclosed from the species *C. thermoaminogenes* and applicants provide no guidance on a correlation between structure and function so as to allow the skilled artisan to make sequences with Rep activity and homologous to SEQ ID NO:4 at the recited levels.

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Nature of the invention. The invention involves making polynucleotides encoding proteins having Rep activity wherein said proteins are at least 90% or 99% homologous to SEQ ID NO:4.

Level of skill in the art. The level of skill in this art is high; however, given the unpredictability of the art, the poorly developed state of the art, the lack of guidance provided by applicants and the scope of the invention, it must be considered that the skilled artisan would have had to have practiced trial and error experimentation in order to try to practice the claimed invention.

Given the above analysis of the factors which the courts have determined are critical in determining whether a claimed invention is enabled, it must be considered that the skilled artisan would have had to have conducted undue and excessive experimentation in order to practice the claimed invention.

Claims 9-10, 12-13, 18, 20 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim an isolated polynucleotide or plasmid comprising a gene encoding a Rep protein, said Rep protein comprising an amino acid sequence that is at least 90% or at least 99% homologous to the amino acid sequence of SEQ ID NO:4 and a method of isolating said plasmid. Applicants provide no disclosure of the functional

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motifs essential for activity of Rep proteins, regions of Rep proteins essential for activity, etc. Applicants disclose four sequences encoding Rep proteins isolated from *C. thermoaminogenes*. The claims read on a genus of nucleic acid sequences encoding proteins at least 90% (or 99%) homologous to SEQ ID NO:4.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention.

In the instant case, applicants claim the recited nucleic acids by function only without a correlation between the structure of the molecules and their function as Rep proteins. Without a determination of the functional motifs which render a polypeptide functional as a Rep protein, the skilled artisan would not be able to envision sequences which encode Rep proteins and are at least 90% or 99% homologous to SEQ ID NO:4. Given the large size of the claimed genus (millions of different molecules) and the absence of guidance on the functional motifs in the Rep proteins, it must be considered that the skilled artisan would not conclude that the four examples disclosed by applicants represent a representative number of species sufficient to describe the claimed genus.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is vague in that applicants recite the plasmid of claim 9 comprising a gene encoding a polypeptide having Rep activity wherein the polypeptide comprises **an amino acid sequence** (i.e. any two or three, etc. stretch of amino acid residues) of SEQ ID NO:4. Since claim 9 recites that the polypeptide be at least 90% homologous to SEQ ID NO:4, it is unclear how the polypeptide can comprise **an (any) amino acid sequence** of SEQ ID NO:4 and also be at least 90% homologous to SEQ ID NO:4?

Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 13 does not further limit claim 9 because the claim recites a plasmid encoding a polypeptide having Rep activity and having **an amino acid sequence** of SEQ ID NO:4. This reads on a plasmid encoding any amino acid sequence (i.e. a sequence of two or three, etc. amino acids) of SEQ ID NO:4; this is a broader limitation than the limitation of having to be at least 90% homologous to SEQ ID NO:4.



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The Drawings filed 8/11/00 are objected to. Figures 1-6 contain numbers, letters and reference characters which are not at least .32 cm (1/8 inch) in height (See 37 CFR 1.84(p)(3)). Corrections to the drawings will not be held in abeyance.

Any rejections not repeated in this Office Action are withdrawn.

No Claims are allowed.


Claims 14-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
July 24, 2004

  
DAVID GUZO  
PRIMARY EXAMINER